JUL 1 4 2004

510(k) Summary

SUBMITTED BY: David Ikeda
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March 31, 2004

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

NAME OF DEVICE:

Trade Name	TSH-CTK-3
Common Name/Description	Immunoradiometric assay (IRMA) for the quantitative determination of Thyrotropin
Classification Name:	Thyroid Stimulating Hormone Test System

PREDICATE DEVICE: Ventrex hTSH ^{125}I IRMA

INTENDED USE: The TSH-CTK-3 is an immunoradiometric assay (IRMA) for the quantitative determination of Thyroid Stimulating Hormone(Thyrotropin) in human serum. Measurements of TSH levels are used as an aid in the diagnosis of thyroid and pituitary disorders.

DEVICE DESCRIPTION: The TSH-CTK-3 is an immunoradiometric assay for the quantitative determination of thyrotropin (TSH) in human serum. Two monoclonal antibodies recognizing different binding sites on the antigen (intact hTSH and β subunit of TSH) are used in excess. The monoclonal antibody to intact hTSH is labeled with Iodine-125 (tracer). The other monoclonal antibody to the β subunit of TSH is immobilized on the inner surface of the tube (coated tube system). During the incubation both antibodies react with TSH molecules of the sample to form a sandwich-type complex bound to the tube (bound fraction B). Unbound tracer is removed with a wash step. After the washing step the radioactivity of the tubes is measured. The radioactivity measured is directly proportional to the TSH concentration of the respective sample. Using samples of known TSH concentration (standards) a radioactivity-concentration-profile (standard curve) is constructed by which TSH values of unknown samples can be determined by means of their respective radioactivity. TSH concentrations in terms of mU TSH/L are calibrated against WHO 2nd IRP 80/558.

TECHNOLOGICAL COMPARISON TO PREDICATE:

Feature	Ventrex hTSH ^{125}I IRMA (K920856)	TSH-CTK-3
Analyte	Thyroid Stimulating Hormone(hTSH)	Thyroid Stimulating Hormone (hTSH)
Intended Use	FOR *in vitro* DIAGNOSTIC USE. The Ventrex hTSH ^{125}I IRMA kit is to be used for the quantitative determination of TSH (thyroid stimulating hormone) concentration in serum.	FOR *in vitro* DIAGNOSTIC USE. The DiaSorin TSH-CTK-3 is an immuno-radiometric assay for the determination of thyrotropin(TSH) in human serum. Measurements of TSH are used as an aid in the diagnosis of thyroid and pituitary disorders.
Assay Type	IRMA	IRMA
Coated Tube	Mouse Monoclonal Anti-hTSH	Mouse Monoclonal Anti-Thyrotropin antibody
Tracer	^{125}I Goat Anti-hTSH	^{125}I Mouse Monoclonal Anti-Thyrotropin antibody
Standards	Eight levels, porcine serum based with nominal concentrations ranging from 0.125-100mIU/L. Standardized against the World Health Organization (WHO) Reference Program 80/558.	Seven levels, human serum based with nominal concentrations ranging from 0.02-0.92mU/L. Standardized against the World Health Organization (WHO) Reference Program 80/558.
Kit Controls	None provided with the kit.	Three levels, human serum based.

PERFORMANCE DATA: A summary of performance data is shown below.

Parameter	Performance Results
Sensitivity (Analytical)	0.04 mU/L
Sensitivity (Functional)	0.09 mU/L
Total Precision(%CV)	2% - 13%
Recovery(mean)	98.7% +/- 1.4%
Linearity	y = 0.93x + 0.52, r = 0.998
Linearity of Dilution	y = 1.02x + 0.19, r = 0.999
Endogenous Substance Interference	No significant interference was observed at the following concentrations: Hemoglobin(500mg/dL), Cholesterol (1000mg/dL) and Bilirubin (15mg/dL). Interference was observed with Triglycerides(330mg/dL)
Sample Types	Serum.
Reference Range(Serum Only)	0.25 - 3.51 mU/L

Analytical Sensitivity was determined from 40 replicates of the zero standard (mean =71cpm). Functional Sensitivity was determined from 14 serum pools assayed in 1 run per day for 5 days (mean 0.09mU/L). Total Precision was determined to be 2% to 13% across the range of the assay according to NCCLS guidelines. Samples diluted linearly with a correlation coefficient of 0.999. Serum and Plasma do show some differences, so the intended use will be for Serum only. Samples frozen for 24 hrs gave similar results for hTSH, as samples stored at 4°C for 24hrs. The method comparison was conducted according to the guidelines in NCCLS reference document EP9-A2. Samples from 95 individuals spanning the assay range were evaluated in both kits. The TSH-CTK-3 assay correlated well with the Ventrex hTSH ^{125}I IRMA kit, with a correlation coefficient of 0.99. The serum sample reference interval was established using 100 apparently healthy adults from Western Europe (0.25 – 3.51 mU/L, 95% confidence intervals).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. David M. Ikeda
DiaSorin Inc.
Manager, Regulatory Affairs & Quality Systems
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Re: k041014
Trade/Device Name: TSH-CTK-3
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid stimulating hormone test system
Regulatory Class: Class II
Product Code: JLW, JIT, JJX
Dated: June 24, 2004
Received: June 29, 2004

Dear Mr. Ikeda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041014

Device Name: TSH-CTK-3

Indications For Use:

The DiaSorin TSH-CTK-3 is an immunoradiometric assay for the quantitative determination of thyrotropin (TSH) in human serum. Measurements of TSH levels are used as an aid in the diagnosis of thyroid or pituitary disorders.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041014